Drug Manufacturing

(SIC 283)

SIGNIFICANT POINTS

- Over half of all workers have a bachelor's, graduate, professional, or Ph.D. degree—roughly double the proportion for all industries combined.
- Forty-one percent of all jobs are in large establishments employing more than 1,000 workers.
- Earnings in drug manufacturing are much higher than those in other manufacturing industries.
- Drug manufacturing is projected to be one of the faster growing manufacturing industries.

Nature of the Industry

The drug manufacturing industry has produced a variety of medicinal and other health-related products undreamed of by even the most imaginative apothecaries of the past. These drugs have saved the lives of millions of people from various diseases, and they permit many ill people to lead reasonably normal lives.

Thousands of medications are available today for diagnostic, preventive, and therapeutic uses. These medicines aid in the control of venereal disease, tuberculosis, influenza, cardiovascular disease, malaria, pneumonia, diabetes, and some forms of cancer. New drugs do much to reduce the severity of mental illness. Vaccines have dramatically reduced the toll of polio, whooping cough, and measles. Discoveries in veterinary drugs have increased animal productivity and controlled various diseases, some of which are transmissible to humans.

The drug industry is comprised of about 1,700 places of employment, which are located throughout the country. These include establishments that make pharmaceutical preparations or finished drugs; biological products, such as serums and vaccines; bulk chemicals and botanicals used in making finished drugs; and diagnostic substances such as pregnancy and blood glucose kits. Pharmaceutical manufacturing firms make up the majority of establishments and employ 60 percent of the workers in this industry.

The American drug industry has achieved worldwide prominence through its research and development of new drugs, and spends a higher proportion of its funds for research than any other industry in the United States. Each year the drug industry tests many thousands of new substances, which may eventually yield only 10 to 20 new prescription medicines.

For the majority of firms in this industry, the actual manufacture of drugs is the last stage in a lengthy process that begins with scientific research to discover new products, and to improve or modify existing ones. The research and development (R&D) departments in drug manufacturing firms start this process by seeking new chemical compounds which have the potential to prevent, combat, or alleviate symptoms of diseases or other health problems. Scientists use sophisticated tools, such as computer simulation and combinatorial chemistry, to hasten and simplify the discovery of potentially useful new compounds. Most firms devote a substantial portion of their R&D budgets to applied research, with the purpose of obtaining and using scientific knowledge to develop a drug targeted to a specific use. For example, an R&D unit may focus on developing a compound that will effectively slow the advance of breast cancer. If the discovery phase yields promising compounds, technical teams then attempt to develop a safe and effective product based on the discoveries. For testing new products in development, a research method called "screening" is used. To screen an antibiotic, for example, a sample is first placed in a bacterial culture. If the antibiotic is effective, it is next tested on infected laboratory animals. Each year, researchers study the effects of potential new medicines on millions of animals, including mice, rats, chickens, and guinea pigs, for evidence of useful—and harmful—effects. A new drug is selected for testing in humans only if it promises to have therapeutic advantages over drugs already in use, or if it offers the possibility of having fewer side effects.

After laboratory screening, firms conduct clinical investigations, or "trials," of the drug on human patients. Human clinical trials normally take place in three phases. First, medical scientists administer the drug to a small group of healthy volunteers in order to determine and adjust dosage levels, and monitor for side effects. If a drug appears useful and safe, additional tests are conducted in two more phases, each phase using a successively larger group of volunteers or carefully selected patients.

Once a drug has successfully passed animal and clinical tests, the Food and Drug Administration (FDA) must review the drug's performance on human patients, the results of which have been carefully documented, before approving the substance for commercial use. The entire process, from the first discovery of a promising new compound to FDA approval, can take up to 15 years, but scientific and information technology advances will shorten that process considerably for many drugs. After FDA approval, problems of production methods and costs must be worked out before manufacturing begins. If the original laboratory process of preparing and compounding the ingredients is complex and too expensive, pharmacists, chemists, chemical engineers, packaging engineers, and production specialists are assigned to develop a process economically adaptable to mass production.

In many production operations, drug manufacturers have developed a high degree of automation. Milling and micronizing machines, which pulverize substances into extremely fine particles, are used to reduce bulk chemicals to the required size. These finished chemicals are combined and processed further in mixing machines. The mixed ingredients may then be mechanically capsulated, pressed into tablets, or made into

solutions. One type of machine, for example, automatically fills, seals, and stamps capsules. Other machines fill bottles with capsules, tablets, or liquids, and seal, label, and package the bottles.

Quality control is vital in this industry. Many production workers are assigned full time to quality assurance functions, whereas other employees may devote part of their time to these functions. For example, although pharmaceutical company sales representatives, called detailers, primarily work in marketing, they engage in quality control when they assist pharmacists in checking for outdated products.

Working Conditions

Working conditions in drug plants are better than in most other manufacturing plants. Much emphasis is placed on keeping equipment and work areas clean because of the danger of contamination. Plants usually are air-conditioned, well lighted, and quiet. Ventilation systems protect workers from dust, fumes, and disagreeable odors. Special precautions are taken to protect the relatively small number of employees who work with infectious cultures and poisonous chemicals. With the exception of work performed by material handlers and maintenance workers, most jobs require little physical effort. In 1997, the incidence of work-related injury and illness was 4.1 cases per 100 full-time workers, compared to 10.3 per 100 for all manufacturing industries and 7.1 per 100 for the entire private sector.

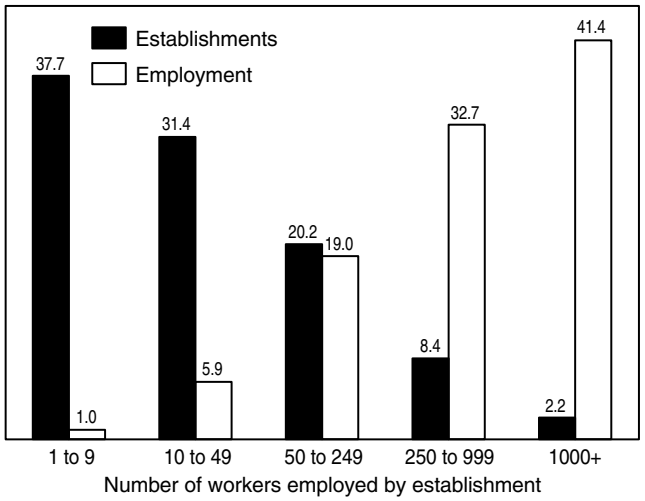
Only 6.5 percent of the workers in the drug manufacturing industry are union members or are covered by a union contract, compared to 15.4 percent of workers throughout private industry.

Employment

In 1998, there were 279,000 wage and salary jobs in the drug industry. Three out of 5 jobs were in establishments that made pharmaceutical preparations (finished drugs), such as tranquilizers, antiseptics, and antibiotics. The remaining jobs were in establishments that made biological products, such as serums, vaccines, toxins, plasmas, and bulk medicinal chemicals and botanicals used in making finished drugs, and for firms making diagnostic substances.

Drug manufacturing establishments typically employ many workers. Over 40 percent of this industry's employees work for firms with more than 1,000 workers (chart). Most jobs were in New Jersey, California, Pennsylvania, New York, North Carolina, Illinois, and Indiana.

Establishments with 1,000 or more workers had over 40 percent of drug manufacturing jobs



Source: U.S. Department of Commerce, *County Business Patterns*, 1997

Occupations in the Industry

About 22 percent of all jobs in the drug industry are in professional and technical occupations (mostly scientists and science technicians), and about 25 percent are in executive and managerial, administrative support, and sales occupations. Over 51 percent of the jobs in the drug industry are in production occupations; these include less skilled operator, fabricator, and laborer occupations and more skilled precision production occupations. The remaining jobs are in service occupations (table 1).

Scientists, engineers, and technicians conduct research to develop new drugs. Others work to streamline production methods and improve environmental and quality control. Life scientists comprise the largest occupation among this industry's scientific and technical workers. Most of these scientists are *biological scientists* who use biotechnology to recombine the genetic material of animals or plants, thus producing new drugs. Biological scientists normally specialize in a particular area. *Biologists* and *bacteriologists* study the effect of chemical agents on infected animals. *Biochemists* study the action of drugs on body processes, by studying the chemical combination and reactions involved in metabolism, reproduction, and heredity. *Microbiologists* grow strains of microorganisms that produce antibiotics. *Physiologists* investigate the effect of drugs on body functions and vital processes. *Pharmacologists* and *zoologists* study the effect of drugs on animals. *Virologists* grow viruses, develop vaccines, and test them in animals. *Botanists*, with their special knowledge of plant life, contribute to the discovery of botanical ingredients for drugs. Other biological scientists include *pathologists*, who study normal and abnormal cells or tissues, and *toxicologists*, who are concerned with the safety, dosage levels, and compatibility of different drugs. Drug manufacturers also employ *medical scientists*, who may also be physicians, to do research, test products, and oversee human clinical trials.

Physical scientists, particularly *chemists*, are also important in the research and development of new drugs. *Organic chemists* combine new compounds for biological testing. *Physical chemists* separate and identify substances, determine molecular structure, help create new compounds, and improve manufacturing processes. *Radiochemists* trace the course of drugs through body organs and tissues. *Pharmaceutical chemists* set standards and specifications for the form of products and for storage conditions; they also see that drug labeling and literature meet the requirements of State and Federal laws. *Analytical chemists* test raw and intermediate materials and finished products for quality.

Science technicians play an important part in both the research for, and the product development of, new medicines. They set up, operate, and maintain laboratory equipment, monitor experiments, analyze data, and record and interpret results. Science technicians usually work under the supervision of scientists or engineers.

Although engineers account for a small fraction of scientific and technical workers, they make significant contributions toward improving quality control and production efficiency. *Chemical engineers* design equipment and devise manufacturing processes. *Bioprocess engineers*, who are similar to chemical engineers, design fermentation vats and various bioreactors for microorganisms that will produce a given product. *Industrial engineers* plan equipment layout and workflow to maintain efficient use of plant facilities. *Mechanical engineers* coordinate the installation and maintenance of sterilizing, heating, cooling, humidifying, and ventilating equipment.

Table 1. Employment of wage and salary workers in drug manufacturing by occupation, 1998 and projected change, 1998-2008

(Employment in thousands)

Occupation	1998 Employment Number	1998 Employment Percent	1998-2008 Percent change
All occupations	279	100.0	10.7
Operators, fabricators, and laborers	97	34.7	7.8
Packaging and filling machine operators	29	10.2	-9.7
Chemical equipment controllers, operators and tenders	24	8.8	12.8
Helpers, laborers, and material movers, hand	14	4.9	9.1
Crushing, grinding, mixing and blending machine operators	8	2.8	35.5
Hand workers, including assemblers and fabricators	6	2.2	12.9
Precision production, craft, and repair	47	16.7	11.3
Blue-collar worker supervisors	15	5.5	12.9
Industrial machinery mechanics	8	2.7	16.2
Inspectors, testers, and graders	7	2.5	-2.2
Maintenance repairers, general utility	4	1.4	2.6
Chemical plant and systems operators	3	0.9	30.9
Professional specialty	41	14.8	22.9
Chemists	14	4.9	12.9
Engineers	8	2.8	17.6
Biological scientists	8	2.7	35.5
Computer systems analysts, engineers, and scientists	4	1.4	58.4
Executive, administrative, and managerial	34	12.3	13.8
Management support occupations	12	4.1	11.7
General managers and top executives	5	1.7	9.6
Engineering, natural science, and computer and information systems managers	4	1.4	32.1
Industrial production managers	4	1.4	20.6
Administrative support, including clerical	28	10.1	1.3
Secretaries	6	2.3	-10.1
Records processing occupations	4	1.4	-4.0
Shipping, receiving, and traffic clerks	3	1.1	3.8
General office clerks	3	1.0	14.0
Technicians and related support	19	6.9	6.2
Science and mathematics technicians	15	5.5	5.8
Marketing and sales	6	2.2	12.9
Service	6	2.0	4.7
Janitors and cleaners	3	1.1	1.6
All other occupations	1	0.3	12.5

At the top of the managerial group are executives who make policy decisions concerning matters of finance, marketing, and research. Other executive, administrative, and managerial workers include *engineering, natural science,* and *computer* and *information systems managers*; *industrial managers*; and *advertising*, *marketing, promotions, public relations,* and *sales managers.*

Administrative support employees include *secretaries*, *general office clerks*, and others who keep records on personnel, payroll, raw materials, sales, and shipments.

Pharmaceutical sales representatives, often called pharmaceutical detailers, describe their company's products to physicians, pharmacists, dentists, and health services administrators. These sales representatives serve as lines of communication between their companies and clients.

Most plant workers can be divided into three occupational groups: Production or processing workers, who operate the drug-producing equipment and inspect the products; maintenance workers, who install, maintain, and repair production equipment; and packers, truckdrivers, and material handlers, who package and transport the drugs.

Many different types of chemical operators are involved in the production of pharmaceutical preparations and biological products. *Pharmaceutical operators* control machines that produce tablets, capsules, ointments, and medical solutions. *Granulator machine operators* tend milling and grinding machines that reduce mixtures to particles of designated sizes. *Compounders* tend tanks and kettles in which solutions are mixed and compounded to make up creams, ointments, liquid medications, and powders. *Compressors* operate machines that compress ingredients into tablets. *Pill* and *tablet coaters*, often called capsule coaters, control a battery of machines that apply coatings to tablets, which flavor, color, preserve, add medication, or control disintegration time. *Tablet testers* inspect tablets for hardness, chipping, and weight to assure conformity with specifications. *Ampoule fillers* operate machines that fill small glass containers with measured doses of liquid drug products. *Ampoule examiners* examine ampoules for discoloration, foreign particles, and flaws in the glass.

After the drug is prepared and inspected, it is bottled or otherwise packaged. Semiskilled workers do most of the packaging and bottle filling with machines that measure exact amounts of the product and seal containers.

Plant workers who do not operate or maintain equipment perform a variety of other tasks. Some drive trucks to make deliveries to other parts of the plant; some load and unload trucks and railroad cars; others keep inventory records. The industry also employs service workers, such as guards and janitors.

Training and Advancement

Training requirements for jobs in the drug industry range from a few hours of on-the-job training to years of formal education, plus job experience; about half of all workers have a bachelor's or graduate degree—roughly double the proportion for all industries combined. The drug industry places a heavy emphasis on continuing education for employees, and many firms provide classroom training in safety, environmental and quality control, and technological advances.

For production and maintenance occupations, drug manufacturers usually hire inexperienced workers and train them on the job; high school graduates are generally preferred.

Beginners in production jobs assist experienced workers and learn to operate processing equipment. With experience, employees may advance to more skilled jobs in their departments.

Many companies encourage production and maintenance workers to take courses related to their jobs in local schools and technical institutes or to enroll in correspondence courses. College courses in chemistry and related areas are particularly encouraged for highly skilled production workers who operate sophisticated equipment. Some companies reimburse workers for part, or all, of their tuition. Skilled production and maintenance workers with leadership ability may advance to supervisory positions.

For science technicians in the drug industry, most companies prefer to hire graduates of technical institutes or junior colleges or those who have completed college courses in chemistry, biology, mathematics, or engineering. Some companies, however, require science technicians to hold a bachelor's degree in a biological or chemical science. In many firms, newly hired workers begin as laboratory helpers or aides, performing routine jobs, such as cleaning and arranging bottles, test tubes, and other equipment.

The experience required for higher-level technician jobs varies from company to company. Usually, employees advance over a number of years from assistant technician, to technician, to senior technician, and then to technical associate, or supervisory technician.

For most scientific and engineering jobs, a bachelor of science degree is the minimum requirement. Scientists who are involved in research and development usually have a master's or doctoral degree. A doctoral degree is generally the minimum requirement for medical scientists, and those who administer drug or gene therapy to patients in clinical trials must have a medical degree. Because biotechnology is not one discipline, but the interaction of several disciplines, the best preparation for work in biotechnology is training in a traditional biological science, such as genetics, molecular biology, biochemistry, virology, biochemical engineering, plant pathology, or botany. Individuals with a scientific background and several years of industrial experience may eventually advance to managerial positions. Some companies offer training programs to help scientists and engineers keep abreast of new developments in their fields and to develop administrative skills. These programs may include meetings and seminars with consultants from various fields. Many companies encourage scientists and engineers to further their education; some companies provide financial assistance for this purpose. Publication of scientific papers also is encouraged.

Drug manufacturing companies prefer to hire college graduates, particularly those with strong scientific backgrounds, as pharmaceutical detailers. Newly employed pharmaceutical representatives complete rigorous formal training programs revolving around their company's product lines.

Earnings

Earnings of workers in the drug industry are higher than the average for all manufacturing industries. In 1998, production or nonsupervisory workers in the drug industry averaged $717 a week, while those in all manufacturing industries averaged $563 a week. Earnings in selected occupations in drug manufacturing in 1997 appear in table 2.

Some employees work in plants that operate around the clock—three shifts a day, 7 days a week. In most plants, workers receive extra pay when assigned to the second or third shift. Because drug production is subject to little seasonal variation, work is steady.

Table 2. Median hourly earnings of the largest occupations in drug manufacturing, 1997

Occupation	Drug manufacturing	All industries
Biological scientists	$22.26	$21.01
Chemists, except biochemists	20.84	21.14
First line supervisors and managers/ supervisors, production and operating workers	20.27	16.62
Chemical technicians and technologists, except health	15.34	14.89
Chemical equipment controllers and operators	14.99	15.25
Secretaries, except legal and medical	14.22	11.00
Production inspectors, testers, graders, sorters, samplers, and weighers	10.78	10.15
Crushing, grinding, mixing, and blending machine operators and tenders	10.77	10.85
Packaging and filling machine operators and tenders	10.52	9.38
Assemblers and fabricators, except machine, electrical, electronic and precision	7.73	9.25

Outlook

Wage and salary jobs in drug manufacturing are expected to increase by about 11 percent over the 1998-2008 period, making it among the faster growing manufacturing industries. Demand for this industry's products is expected to remain strong. Even during times of fluctuating economic conditions, there will be a market for over-the-counter and prescription drugs, including the diagnostics used in hospitals, laboratories, and homes; the vaccines used routinely on infants and children; analgesics and other symptom-easing drugs; and antibiotics and "miracle" drugs for life-threatening diseases. Although the use of drugs, particularly antibiotics and vaccines, has contributed towards eradicating or limiting a number of deadly diseases, many others, such as cancer, Alzheimer's, and heart disease, continue to elude cures. On-going research and the manufacture of new products to combat these diseases will continue to contribute to employment growth. Because so many of the drug industry's products are related to preventive or routine health care, rather than just illness, demand is expected to increase as the population expands. Demand will be further stimulated by the growing number of older people who will require more health care services and by the growth of both public and private health insurance programs, which increasingly cover the cost of drugs and medicine. Other factors expected to increase the demand for drugs include greater personal income and the rising health consciousness and expectations of the general public. Biotechnological research continues to offer possibilities for the development of new drugs and products to combat illnesses and diseases which have previously been unresponsive to treatments derived by traditional chemical processes. Scientists will also use biotechnology to develop new antibiotics for use against increasingly drug-resistant bacteria.

Drug producers and buyers are expected to place more emphasis on cost-effectiveness, due to concerns about the cost of health care, including prescription drugs. Growing

competition from the producers of generic drugs may also exert cost pressures on many firms in this industry. These factors, combined with continuing improvements in manufacturing processes, are expected to result in slower employment growth over the 1998-2008 period than occurred during the previous 10-year period.

Faster than average growth is anticipated for professional specialty occupations—especially the biological and medical scientists engaged in research and development, the backbone of the drug industry, and computer systems analysts, engineers, and scientists. Slower than average overall growth is projected for operators, fabricators, and laborers. Average growth is projected for skilled mechanics, who service the growing amount of automatic processing and control equipment. Employment of administrative support and clerical workers is expected to experience little or no change, as companies streamline operations and increasingly rely on computers.

Unlike many other manufacturing industries, drug industry employment is not highly sensitive to changes in economic conditions. Even during periods of high unemployment, work is likely to be relatively stable in this industry.

Sources of Additional Information

For additional information about careers in drug manufacturing and the industry in general, write to the personnel departments of individual drug manufacturing companies.

For information about careers in biotechnology, contact:

- Biotechnology Industry Organization, Suite 1100, 1625 K St. NW., Washington, DC 20006.
  Internet: **http://www.bio.org**

Information on these key drug manufacturing occupations may be found in the 2000-01 *Occupational Outlook Handbook*:

- Biological and medical scientists
- Chemists
- Computer scientists, computer engineers, and systems analysts
- Engineers
- Inspectors, testers, and graders
- Science technicians